



## Vinyl Polysiloxane Impression Materials

### General Information

I-SiL™ offers full line up of vinyl polysiloxane based dental impression materials designed to meet the specific characteristic requirements needed for crowns, bridges, orthodontics, and implants. The superior hydrophilicity of all I-SiL™ products results in highly accurate imprints, in moisture persistent clinical settings like bleeding, salivation, tissue exudation, and subgingival margins.

### Composition

- Organic Matrix : Polymethyl hydrogen siloxane, Polymethyl siloxane, Polyvinyl siloxane
- Inorganic Fillers : Nano Silica
- Additives : Initiator, Catalyst, Stabilizer, Others

### Indications

- Crown and bridge impressions
- Inlay and onlay impressions
- Implant impressions
- Functional impressions
- Pressure point identification
- Denture impressions
- Study model impressions

### Shade

Product	Packing type	Shade
Light body (I-SiL™, Secret)	Cartridge	Orange
Regular body (I-SiL™, Jumbo)	Cartridge	Sky blue
Heavy body (I-SiL™, Jumbo)	Cartridge	Blue
Premium Putty	Jar	Purple

### Precautionary Information

- Check the expiration date and appearance condition of product and package.
- Observe the instruction for use after being well acquainted with the instruction for use.
- Do not use if the material has been cured.
- If contamination chemicals known to inhibit setting of silicone materials are present, completely remove.

### Application

#### Cartridge Type (Heavy Body, Regular Body, Light Body)

- Insert the cartridge into the dispenser.
- Squeeze little bit until base and catalyst drain together without blocking.
- Insert the mixing tip into the cartridge and turn it 90 degree to the clock wise direction.
- Pull the trigger slowly for good mixing of the materials.
- The tray must be seated before the end of the working time.
- Put the mixed materials on the tray.
- Remove the tray after 4 minutes.

#### Jar Type (Putty)

- Take out proper amount of base and catalyst by measuring spoon.
- Mix the materials with hand until the color becomes equal.
- Put the mixed materials on the tray.
- Remove the tray after 4 minutes.

#### Working time, Setting time

Product	Packing type	Working time(min)	Setting time(min) (intra oral)
Light body (I-SiL™, Secret)	Cartridge	≥ 1.5	≤ 4.0
Regular body (I-SiL™, Jumbo)	Cartridge	≥ 1.5	≤ 4.0
Heavy body (I-SiL™, Jumbo)	Cartridge	≥ 1.5	≤ 4.0
Premium Putty	Jar	≥ 1.5	≤ 4.0

\* Test Conditions : Temperature (23°C ± 2°C), Relative humidity (50 ± 5%)

#### Sterilization

- After remove the impression materials from the mouth, make sure to wash it.
- Keep 30 min. for sterilization in the 2% glutaraldehyde (acidic), 0.5~1.5% Sodium hypochlorite or 0.1~1.5% Providone-iodine.

#### Plaster Pouring

- Pour the plaster at least 30 minutes after removal of the impression materials from the mouth for the best plaster model.

Note) Recovery time for the impression material : about 30 minutes.  
H<sub>2</sub> Gas development time : 5~15 minutes (H<sub>2</sub> gas development time of the vinyl impression material could be various depending on the products.  
To prevent air bubble, wait for 30 minutes for plaster pouring.)

### Manufacturer

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### EU representative

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### Caution

- I-SiL™ is designed for sale and use by licensed dental care professionals only. It is not designed for sale nor is it suitable for use by non-dental care professionals
- Working time includes mixing time.
- There could be about 15 seconds difference (faster or later) of working time and setting time per one Degree °C temperature change.
- Latex glove may disturb hardening of the impression materials, please use well-washed hands or vinyl glove(Putty).
- Avoid surface contact or contamination with chemicals known to inhibit the set (e.g. acrylate and methacrylate residues – Oxygen inhibition layer of composite materials, latex rubber, and sulfur compounds, Eugenol materials, Hemostatic, Glycerine, etc.).
- If contamination chemicals known to inhibit setting of silicone materials are present, completely remove. (If acrylic and methacrylate residues are present, clean the affected tooth surface with isopropyl alcohol before making the impression. If contamination from latex rubber or sulfur is suspected, rinse the area with an aqueous solution of hydrogen peroxide before making the impression.)
- Organic solvents may cause inaccurate impressions.
- Care should be taken to avoid getting material on clothing. It is hard to remove when it sets up on clothes.
- DO NOT use I-SiL™ after the indicated expiration date on the product.
- If I-SiL™ causes an allergic reaction or oversensitivity, discontinue its use immediately.
- Avoid contact of I-SiL™ with eyes, mucosal membrane, skin and clothing.
- If I-SiL™ has been in contact with the eyes, thoroughly flush eyes with water and immediately contact an ophthalmologist.
- If refrigerated storage is used, allow product to reach room temperature prior to use.

### Storage & Use

- Do not expose the I-SiL™ to elevated temperatures, or to intense light.
- Store I-SiL™ at a temperature between 2~27°C/35.6~80.6°F.
- Ambient temperatures routinely higher than 27°C/80.6°F may reduce shelf life.
- Shelf life at room temperature is 24 months.
- See outer package for expiration date.
- Do not store materials in proximity to products containing chemicals known to inhibit setting of silicone materials (e.g. acrylate and methacrylate residues – Oxygen inhibition layer of composite materials, latex rubber, and sulfur compounds, Eugenol materials, Hemostatic, Glycerine etc.).

### Warranty

Spident® warrants this product will be free from defects in material and manufacture. Spident®, MAKES NO OTHER WARRANTIES INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. User is responsible for determining the suitability of the product for user's application. If this product is defective within the warranty period, your exclusive remedy and Spident®'s sole obligation shall be repair or replacement of the Spident®'s product.

### Limitation of Liability

Except where prohibited by law, Spident® will not be liable for any loss or damage arising from this product, whether direct, indirect, special, incidental or consequential, regardless of the theory asserted, including warranty, contract, negligence or strict liability.

### Customer Information

No person is authorized to provide any information which deviates from the information provided in this instruction sheet.

Caution: U.S. Federal Law restricts this device to sale or use on the order of a dental professional.

### Disposal

It should be handled according to local laws and regulations.

Conformity with CE Comunaute Europeenne			
23°C ± 2°C	Temperature limit	LOT	Batch code
⚠	Caution	📅	Date of Manufacture
☀	Keep dry	🕒	Used-by date
☀	Keep away from sunlight	📖	Consult Instructions for Use
🏭	Manufacturer	MD	Medical Device
EC REP	Authorized representative in the European community		
Rx Only	Federal law prohibits dispensing without a prescription		